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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,999	03/16/2001	David M. Neville	14028.0284U2	7991
36339	7590	10/14/2005	EXAMINER	
NATIONAL INSTITUTE OF HEALTH C/O NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30303			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/810,999

Applicant(s)

NEVILLE ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,8,10,12,13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 4,8,10,12,13 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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#### DETAILED ACTION

1. Applicant's amendments and remarks, filed 8/04/05, are acknowledged. In view of Applicant's amendments the previous rejections under the first and second paragraphs of 35 U.S.C. 112 have been withdrawn.

2. Claims 4, 8, 10, 12, 13, and 15 are being acted upon.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4, 8, 10, 12, 13, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,103,235 (IDS), for the reasons of record as set forth in the paper mailed 5/20/03 and maintained in the papers mailed 4/07/04 and 4/01/05.

Applicant's arguments, filed 8/04/05, have been fully considered but are not found persuasive. Applicant argues that in view of the instant amendment, the instant application is entitled to priority to Application No. 08/439,409, now U.S. Patent No. 6,103,235, thus, the '235 patent is not available as prior art.

Applicant is advised that the instant claims are denied the benefit of priority of the '409 application. The '409 application discloses pancreatic islet cell transplantation in a more limited scope than is claimed here. Pancreatic islet cell transplantation is disclosed just once in the application. Said transplantation is disclosed only wherein the donor is a cadaver and only in a context wherein an immunotoxin is administered 0 to 6 hours before transplantation. The broader and more generic method of the instant claims is not disclosed. Accordingly, while the '235 patent renders the method of the instant claims obvious, the instant claims are not granted the benefit of priority to the '409 application. The priority date of Claims 4, 8, 10, 12, 13, and 15 is the priority date of parent application 09/064,413, 4/22/98.

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5. Claims 4, 8, 10, 12, 13, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/32137 (1996, IDS), in view of Henretta et al. (1994, IDS), for the reasons of record as set forth in the paper mailed 5/20/03 and maintained in the papers mailed 4/07/04 and 4/01/04.

Applicant arguments, filed 8/04/05, have been fully considered but are not found persuasive. Applicant argues that given the new priority date, PCT/US96/05087 (WO 96/32137), cannot be used as prior art. See section 4 above regarding the denial of the benefit of priority.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4, 8, 10, 12, 13, and 15 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method employing a divalent anti-CD3 diphtheria toxin binding mutant immunotoxin... (Claim 13).

B) A method of transplanting pancreatic islet cells to a subject in need thereof comprising administering to the subject a divalent anti-CD3 diphtheria toxin binding site mutant immunotoxin... (Claim 15).

Applicant argues that support for Claim 13 can be found in original Claims 5-7 and throughout the specification; no specific support is cited for Claim 15.

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Regarding A) Applicant is advised that original Claims 5-7 recite a divalent anti-T cell immunotoxin directed at the CD3 epitope, wherein the toxin moiety is diphtheria toxin.


Regarding B) except for the disclosure in the last paragraph at page 8, the specification discloses only a method of pancreatic islet cell transplantation as a treatment for diabetes; additionally, no support for a divalent anti-CD3 diphtheria toxin binding site mutant immunotoxin has been found.

9. No claim is allowed.

10. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

  
10/16/05

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600